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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,374	03/10/2004	Jeffrey O. Phillips	04242350	4467
26565 7590 06/13/2007 MAYER, BROWN, ROWE & MAW LLP 71 S. WACKER CHICAGO, IL 60606			EXAMINER CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/797,374

Applicant(s)

PHILLIPS, JEFFREY O.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 151-154, 156-159, 163, 165-170, 172-178, 180 and 182-236 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 151-154, 156-159, 163, 165-170, 172-178, 180 and 182-236 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Amendment and response filed by applicants dated Mar. 21, 2007 have been entered and considered carefully.

Claims 1-150, 155, 160-162, 164, 171, 179, 181 have been canceled. Claims 151-154, 156-159, 163, 165-170, 172-178, 180, 182-236 as currently amended are pending.

2. The rejection of claims 151-154, 156-159, 163, 165-170, 172-178, 180, 182-236 under 35 USC 112 second paragraph is maintained for reasons of record.

As it was explained in the previous office action, the insertion of the 1 mg to 100 mg for an "orally deliverable" composition does not obviate the issued. Please note that it was clearly explained that orally deliverable to give a plasma concentration of omeprazole at 0.1 µg/mg at about 30 minutes does not define the composition. Does it mean a unit dosage falls within the range of 1-100 mg given repeated times, multiple units or single dosage. In addition, a plasma concentration is related to the body weight, previous treatment etc., of the subject.

The proviso conditions further confuses the scope, for example, the claim provisos out aluminum hydroxide-sodium carbonate co-precipitate, then does the product aluminum hydroxide and sodium bicarbonate mixture within the scope or not within the scope? Please note co-precipitation is one way of forming a mixture. It is recommended that the claims are particularly pointing to what is the composition instead of what is not.

3. Claim 151 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The emended term "at least a portion of which is not enteric coated" finds no antecedent basis and is considered NEW MATTER. Please note that there is no description or definition as to what constituted "at lease a portion" of the omerprazole is not enteric coated. "A portion of

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the omeprazole is not enteric coated” being the sole “active” ingredient in a composition, is an inventive concept lacking description or definition from the specification.

Removal of new matter is required. In re Russmussen 211 USPQ 325.

4. The rejection of 151-154, 156-159, 163, 165-170, 172-178, 180, 182-236 under 35 USC 112 first paragraph for failing to comply with the enablement requirement is maintained for reason of record.

Applicants merely argued that one can administer the claimed composition to attain the claimed blood levels without factual evidence. Please note that it was very clearly delineated in the previous office action that the outcome of plasma concentration in different species of animals which differ in genetic/metabolic response to the drug, body weight, pre-condition, etc. Therefore, the composition must be administered in the target subject *first* before acquiring what is the composition. In addition, with the current amendment of 1-100 mg omeprazole, there is no evidence that such a dosage would be operable to a 25 gm body weight mice as well as a 600 kg body weight gorilla.

It is recommended that the composition be claimed as what it is not what it does. Functional limitation may be employed when the field of endeavor is predictable such as mechanical or electrical inventions. Biological systems have been well established to be highly unpredictable.

5. The rejection of claims 151-154, 156-159, 163, 165-170, 172, 175 under 35 USC 102(b) is maintained for reason of record.

As it was clearly delineated supra that the amendment to claim 151 contains new matter. After removal of new matter and the claims would be the pre-amendment version, the rejection is still applicable.

6. The rejection of claims 151-154, 156-159, 163, 165-170, 172-178, 180, 182-236 under 35 USC 103(a) is maintained for reason of record.

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The gist of applicants argument is that the prior art are co-administration of separate formulation which is different from the instant claims thus cannot render the instant claims prima facie obvious.

Applicants attention is drawn to the well established guidelines set forth by the court in In re Kerkhover 205 USPQ 1069, Ex parte quadranti 25 USPQ2d 1071, Ex parte the NutrSweet Co., 19 USPQ2d 1586, wherein two composition for the same purpose are combined to form a third composition is prima facie obvious. In the instant case, clearly motivation/suggestion was also explicitly pointed in the previous office action by Waring.

Applicants disclosure, explicitly support such a combination since example III contains a inner composition of PPI and a separate outer composition of sodium bicarbonate, thus, the mere physical combination of the two prior art product to be co-administer in one "package".

7. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

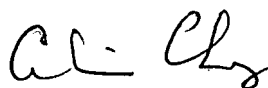
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jun. 7, 2007

A handwritten signature in black ink, appearing to read 'Celia Chang'.

Celia Chang
Primary Examiner
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